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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,363	06/15/2001	Eugene J. Alexander	STAN-144/01US	6739

36806 7590 05/05/2006  
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EXAMINER

FOREMAN, JONATHAN M

ART UNIT PAPER NUMBER

3736

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/882,363	ALEXANDER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jonathan ML Foreman	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 December 2005.  
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 36-43, 45-47, 49, 51, 52 and 54-68 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 36, 42, 43, 45-47, 49, 51, 52 and 54-68 is/are rejected.  
7) ☒ Claim(s) 37-41 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 36, 42, 43, 61 and 64 are rejected under 35 U.S.C. 102(a) as being anticipated by Eckstein et al. (1998 AJR 170; 593 – 597).

In regards to claims 36, 42, 43, 61 and 64, Eckstein et al. discloses assessing the change of cartilage in a living human knee joint including determining the thickness or volume of a region of cartilage at an initial time and a later time; determining the change in thickness or volume of the cartilage between the initial and later time (Page 597, Col. 1, 1<sup>st</sup> complete paragraph); electronically transferring an electronically generated image from a transferring device to a receiving device located distant the transferring device, receiving the transferred image at a distant location; and converting the transferred image to a degeneration pattern (Page 594, “Digital Image Processing”).

Claims 49, 51 and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,320,102 to Paul et al.

In regards to claims 49, 51 and 52, Paul et al. discloses making a three-dimensional map of joint cartilage (Col.4, lines 31 – 34; Col. 5, lines 28 – 32) of a human knee joint including measuring a detectable biochemical component selected from the group consisting of glycosaminoglycan, sodium, water and hyaluronic acid (Col. 8, line 52 – Col. 9, line 18); mapping the amounts of the biochemical component in three dimensions (Col.4, lines 31 – 34; Col. 5, lines 28 – 32; Col. 10, lines

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40 - 64); determining the relative amounts of the biochemical component and determining abnormal joint cartilage by identifying the areas having altered amounts of the biochemical component present (Col. 11, lines 27 **60/112989** – 42).

Claims 36, 42, 43, 45 – 47 and 61 – 68 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,560,476 to Pelletier et al.

In reference to claims 36, 42, 43, 45 – 47 and 61 – 68, Pelletier et al. discloses a method of assessing the change of thickness, width, area and volume of cartilage in a human knee (Col. 9, lines 48 – 51) using MRI imaging including: determining the thickness of the cartilage comprising normal and diseased cartilage at an initial time, at a later time and determining the change in the thickness between the initial and later times; transferring the electronically generated image from a transferring device to a receiving device; receiving the transferred image at the distant location; and converting the transferred image to a degeneration pattern (Col. 14, line 13 – Col. 15, line 23). Pelletier et al. discloses placing external markers on the skin overlaying the bone on either side of the joint (Col. 4, lines 10 – 15). The MRI technique employs spoiled gradient echo (Col. 11, line 39) and obtains a series of two-dimensional views of the joint, which are integrated to give a three-dimensional image.

Claims 57 - 60 are rejected under 35 U.S.C. 102(a) as being anticipated by Kshirsager et al. (Investigative Radiology, vol. 33, no. 5).

In regards to claims 57 – 60, Kshirsager et al. discloses a method of estimating a change of cartilage in a knee joint (289, Col. 2) including defining a 3D object coordinate system at an initial time T1; identifying a region of cartilage defect or diseased cartilage within the 3D object coordinate system; defining a volume of interest around the region of the cartilage defect or diseased cartilage whereby the volume of interest is equal to or larger than the cartilage defect, but does not encompass the entire articular cartilage (294, Col. 2, Focal Cartilage Volume); defining a 3D object

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coordinate system of the joint at a second timepoint, T2; placing the identically-sized volume of interest into the 3D coordinate system at timepoint T2 using the object coordinates of the volume of interest at timepoint T1; and measuring any differences in cartilage within the volume of interest at timepoints T1 and T2 (289, Col. 2; 290, Col. 2, Materials and Methods; Page 296, table 1).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 45 – 47 and 65 – 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eckstein et al. in view of U.S. Patent No. 5,427,099 to Adams.

In regards to claims 45 – 47, 65 and 68, Eckstein et al. discloses assessing the change of cartilage in a living human knee joint including determining the thickness or volume of a region of cartilage at an initial time and a later time using a magnetic imaging technique (MRI); determining the change in thickness or volume of the cartilage between the initial and later time (Page 597, Col. 1, 1<sup>st</sup> complete paragraph). The MRI technique disclosed by Eckstein et al. creates a three-dimensional image which inherently involves first obtaining a series of two-dimensional views that are integrated to create the three-dimensional image. Eckstein et al. discloses the MRI technique employing a gradient echo, spin echo, fast-spin echo, driven equilibrium forier transform, spoiled gradient echo or steady state free precession technique (Page 594, “Subjects and Methods”). However, Eckstein et al. fails to disclose placing external markers on the skin overlying the bone on either side of the joint. Adams discloses a marker for use with an MRI to be placed on the skin of

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an area of interest (Col. 3, lines 44 – 52). It would have been obvious to one having ordinary skill in the art to modify the method as disclosed by Eckstein et al. to include the step of applying a marker or markers as taught by Adams on either side of the joint locate the area of concern, allowing for a narrower focus in the MRI (Col. 3, lines 52 – 57).

In regards to claims 66 and 67, Eckstein et al. in view of Adams discloses determining the thickness or volume of cartilage and determining a change in thickness or volume of cartilage (Page 597, Col. 1, 1<sup>st</sup> complete paragraph). However, Eckstein et al. in view of Adams fails to disclose determining the width or area of cartilage or determining the change in width or area of cartilage. However, it is well known in the art that width and area of cartilage are desirable measurements commonly made using MRI imaging. It would have been obvious to one having ordinary skill in the art to modify the method as disclosed by Eckstein et al. in view of Adams to include the step of measuring and determining the change in width or area of cartilage if desired.

Claims 54 – 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,320,102 to Paul et al. as applied to claim 49 above, and further in view of U.S. Patent No. 5,427,099 to Adams.

In regards to claims 54 – 56, Paul et al. discloses an MRI technique to create a three-dimensional image which inherently involves first obtaining a series of two-dimensional views that are integrated to create the three-dimensional image. Paul et al. discloses the MRI technique employing a gradient echo, spin echo, fast-spin echo, driven equilibrium forier transform, spoiled gradient echo or steady state free precession technique (Page 594. “Subjects and Methods”). However, Paul et al. fails to disclose placing external markers on the skin overlying the bone on either side of the joint. Adams discloses a marker for use with an MRI to be placed on the skin of an area of interest (Col. 3, lines 44 – 52). It would have been obvious to one having ordinary skill in

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the art to modify the method as disclosed by Paul et al. to include the step of applying a marker or markers as taught by Adams on either side of the joint locate the area of concern, allowing for a narrower focus in the MRI (Col. 3, lines 52 – 57).

Claims 62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eckstein et al.

In regards to claims 62 and 63, Eckstein et al. discloses determining the thickness or volume of cartilage and determining a change in thickness or volume of cartilage (Page 597, Col. 1, 1<sup>st</sup> complete paragraph). However, Eckstein et al fails to disclose determining the width or area of cartilage or determining the change in width or area of cartilage. However, it is well known in the art that width and area of cartilage are desirable measurements commonly made using MRI imaging. It would have been obvious to one having ordinary skill in the art to modify the method as disclosed by Eckstein et al to include the step of measuring and determining the change in width or area of cartilage if desired.

#### ***Allowable Subject Matter***

Claims 37 – 41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Response to Arguments***

Applicant's arguments filed 2/27/05 have been fully considered but they are not persuasive. In regards to Eckstein et al., Applicant asserts that Eckstein et al. neither specifically teaches nor suggests with an enabling disclosure an operative system and method capable of determining the change in thickness or volume of cartilage over time. Applicant additionally asserts that Eckstein et al. studied volunteers who had no musculoskeletal disorders or internal derangements of the knee,

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and therefore cannot disclose creating a degeneration pattern. However, the Examiner disagrees. A reference contains an “enabling disclosure” if the public was in possession of the claimed invention before the date of invention. “Such possession is effected if one of ordinary skill in the art could have combined the publication’s description of the invention with his [or her] own knowledge to make the claimed invention.” *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985).

MPEP 2121.01 R-3. Eckstein et al. clearly discloses determining the thickness, width, or volume of a region of cartilage at an initial time and a later time (See Subjects and Methods) and determining the change in thickness (See Results), width or volume between the initial and later times and converting an image to a degeneration pattern (Page 594, Col. 2, 2<sup>nd</sup> Paragraph). The method steps as claimed require no particular order. In regards to Paul et al., Applicant asserts that Paul et al. fails to disclose making a three-dimensional map of joint cartilage. However, a three-dimensional map of the joint cartilage is made (Col. 4, lines 31 – 34; Col. 5, lines 28 – 32). The claim does not require a three-dimensional display. In regards to Pelletier et al., Applicant asserts that Pelletier et al. is not a proper reference because of the earliest date entitled to Pelletier et al. is November 1, 1999, and that Applicant claims priority to a provisional application filed December 16, 1998. However, the claims in the pending application are not supported by the provisional application filed December 16, 1998. Therefore, Applicant is only entitled to a filing date of December 16, 1999. As a result, Pelletier et al. is a proper reference under 35 U.S.C. § 102(e). Applicant asserts that Pelletier et al. fails to disclose transferring, receiving and converting the transferred image. However, the Examiner disagrees. At Col. 12, lines 43 – 46, Pelletier et al. discloses transferring, receiving and converting a transferred image. In regards to Kshirsager et al., Applicant asserts that Kshirsager et al. fails to disclose computing difference in overall cartilage volume over time. However, the claim does not require the computing of the difference in overall cartilage volume over time. Claim 57 merely



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recites “measuring any differences in cartilage within the volume of interest between timepoints  $T_1$  and  $T_2$ ”. Table 1 shows multiple measurements performed over a period of time. Any difference in cartilage volume over time is contained within the measurements.

### *Conclusion*

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

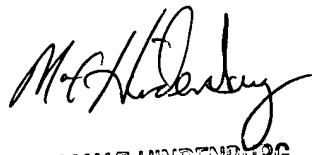
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan ML Foreman whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
JMLF

  
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